UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/147,165	12/14/2011	Sergey Dzekunov	MAXC.P0032US/11107561	1317

32425 7590 11/29/2016

NORTON ROSE FULBRIGHT US LLP
98 SAN JACINTO BOULEVARD
SUITE 1100
AUSTIN, TX 78701-4255

EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
11/29/2016	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

aoipdocket@nortonrosefulbright.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SERGEY DZEKUNOV

Appeal 2014-007261
Application 13/147,165[1]
Technology Center 1600

Before TONI R. SCHEINER, DONALD E. ADAMS, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims directed to electroporation methods. The Examiner rejected the claims under 35 U.S.C. § 102 and § 103(a). We have jurisdiction under 35 U.S.C. § 134. The Examiner's decision is affirmed.

STATEMENT OF THE CASE

The claims in this appeal are directed to a method of electroporation. The Application explains that electroporation is a process of using an electrical field to load living cells, cell particles, or lipid vesicles, with extracellular material. '165 Application ¶ 3.

---

[1] "The '165 Application." The real party in interest is listed in the Appeal Brief as Maxcyte, Inc. Appeal Br. 1.

Appellant appeals from the Examiner's final rejection of claims 1–9 and 11. The claims stand finally rejected by the Examiner as follows:

1. Claims 1, 2, 6, 7, 9, and 11 under 35 U.S.C. § 102(b) (pre-AIA) as anticipated by Hui and Li (*In Vitro and Ex Vivo Gene Delivery to Cells by Electroporation*, 37 METHODS IN MOLECULAR MEDICINE 157–171 (2000)) ("Hui"). Final Rej. 3

2. Claims 2–5 and 8 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Hui. Final Rej. 6.

Claim 1, the only independent claim on appeal, is reproduced below:

1. An electroporation method comprising:

> (a) determining electroporation parameters such that during an electrical pulse a first time constant representative of electrical conductivity increase in electroporation medium (t_1) during the pulse is not less than a second time constant representative of capacitor discharge (t_2), wherein the pulse duration is less than either t_1 or t_2; and
>
> (b) applying one or more electrical pulses under the electroporation parameters to a sample to be electroporated.

CLAIM INTERPRETATION

The anticipation rejection in this appeal turns on the interpretation of claim 1. Consequently, we begin with claim interpretation. During patent examination:

> [T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.

In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Claim 1 recites two steps. In the first step (a), "electroporation parameters" are determined. In the second step (b), electrical pulses are applied to a sample "under the electroporation parameters."

Step (a) has a "determining" step of the electroporation parameters. We interpret "determining" to mean that a parameter is ascertained. This interpretation is consistent with the written description of the '165 Application which discloses that the "dimension of the electroporation chambers will be considered in determining the parameter for optimal electroporation." '165 Application ¶ 119. In other words, the "determining" step can merely be selecting a component of the process that possesses a value that constitutes a parameter of the electroporation method.

Claim 2, which depends from claim 1, further recites "wherein the electroporation parameters comprise buffer conductivity, power supply capacitance, electroporation chamber geometry, and electric field strength." Thus, selecting a buffer, a power supply, and an electroporation chamber to be used in the electroporation method is "determining" electroporation parameters.

The claim requires that the electroporation parameters are determined "such that during an electrical pulse" [1] a first time constant is not less than a second time constant; and [2] the pulse duration is less than the first time constant or the second time constant.

We interpret that phrase "such that"[2] to indicate that, as a result of "determining electroporation parameters," conditions [1] and [2] are met.

---

[2] Definition 2 (attached) from http://www.macmillandictionary.com/us/dictionary/american/such.

The Application discloses equations for calculating the recited time constants. Appeal Br. 1 (citing '165 Application ¶¶ 75, 81.) However, we do not interpret the claim to require that the time constants be calculated by such equations, or even ascertained, because there is no active step recited in the claim that would require it. The claim does not recite an equation or algorithm that must be performed to calculate the time constants for the electroporation parameters. The only requirement of the claim is that, when the parameters are determined, conditions [1] and [2] must be met.

The claim also does not require recognition that conditions [1] and [2] have been met when the pulse is applied in step (b) under the electroporation parameters of step (a). The "such that" language in the claim indicates that as result of determining the parameters conditions [1] and [2] are met, but the language does not dictate that it would have been recognized.

In sum, we discern no language in the claim that would require the time constants to be calculated, ascertained, or even explicitly recognized by the skilled worker when carrying out the electroporation method.

ANTICIPATION REJECTION

The Examiner found that Hui describes an electroporation process in which electroporation parameters are optimized in order to improve the efficiency of transfecting DNA into cells. Final Rej. 4–5. Hui recognized that field strength E (at p. 159 (3); p. 160, ll. 7–9, 21–23; paragraph spanning pp. 160–161; p. 161; p. 167: "Since the transfection efficiency is proportional to *ET*, there is a choice of optimizing either *E* or *T*") and capacitance (p. 163: "Many electroporation protocols give electric parameters in terms of voltage and capacitor value") are electroporation

parameters, both of which are expressly recited in dependent claim 2. *See* Final Rej. 5.

The Examiner found that Hui provided an example in which the field strength E was 0.5–2kV/cm and the pulse time was T=0.14 milliseconds (Hui, p. 163, Fig. 2 legend). Final Rej. 3, 5. *See also* Hui, p. 162, Fig. 1. Since these values fall within the ranges recited in dependent claims 6 and 7, the Examiner found that Hui anticipated the claims. Final Rej. 3–4, 5.

Appellant contends that Hui does not anticipate the claims because Hui does not disclose the first and second time constants recited in claim 1. Appeal Br. 3–4. Appellant states that "[w]hile Hui may disclose altering electroporation parameters, it does not disclose determining electroporation parameters in the way described by claim 1, nor does it suggest such a determination." *Id.* at 4–5. Appellant contends that the phrase "such that" means that the time constants must be determined to meet all the claim requirements. Reply Br. 1, 3–4.

Appellant's argument does not persuade us that the Examiner erred. While we agree with Appellant that the time constants [1] and pulse duration [2] must be met in order for the claim to be anticipated, Appellant did not provide sufficient support for the position that Hui must explicitly disclose the time constants to anticipate the claim. *Id.* at 3. We have not been directed to language in the claim that would require the time constants to be calculated or ascertained when the claimed process is accomplished. As explained in the *Claim Interpretation* section, we interpreted the claim to require that the time constants must be met under the specific parameters utilized during electroporation. However, based on the plain language of the claim, we did not interpret the claim to require recognition by the person

carrying out the recited method that the time constant conditions were achieved. The issue is whether the Examiner met the burden of providing a sound basis for believing that Hui's parameters met the conditions of claim 1.

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). When the limitations of a claim are not expressly described in the prior art, the PTO must show "sound basis for believing" that despite the failure of the prior art to describe them, the limitations are inherently there and "the products of the applicant and the prior art are the same." *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990).

In this case, as discussed above, the Examiner established that Hui disclosed electrical fields and pulse times that meet the corresponding parameter values in claims 6 and 7. Final Rej. 3–4, 5. The parameters are determined "such that during an electrical pulse" [1] a first time constant is not less than a second time constant; and [2] the pulse duration is less than the first time constant or the second time constant. Because the claimed electric field parameter is met by Hui, it is logical that the time constants would also be met because the parameters appear to determine the time constants. Under such disclosed electric field parameter and utilizing a pulse time of claim 7, it would also be logical that the time constants are met for the same reason. Thus, the Examiner had a sound basis for believing that Hui inherently utilized the time constant conditions recited in claim. S*pada*, 911 F.2d at 708; *Schreiber*, 128 F.3d at 1477. When such circumstances are met, the burden shifts to applicant to show that the limitations are not met by the prior art. *Id.*

Appellant did not provide persuasive argument or rebuttal evidence that the Examiner's fact-based determination was in error. Appellant argues that the Examiner has not pointed to any disclosure in Hui where such a relationship between time constants is taught. Appeal Br. 4; Reply Br. 3–4. However, Appellant failed to acknowledge that anticipation can be found when a process "inherently" meets a claim limitation (*Schreiber*, 128 F.3d at 1477), namely, when the recited limitation is a necessary result of carrying out the process.

Appellant states that "is entirely possible that one of ordinary skill in the art practicing Hui could apply a pulse to a sample for the allegedly anticipatory duration (i.e., 140 microseconds) while the allegedly anticipatory duration is ***greater than*** t_1 or t_2." Appeal Br. 5.

Appellant did not provide factual support for this statement. It is well-established that an argument made by counsel in a brief does not substitute for evidence lacking in the record. *Estee Lauder, Inc. v. L'Oréal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997).

Because Hui carries out electroporation and describes parameters and pulse times that fall within the scope of the claims, the Examiner reasonably shifted the burden on Appellant to show that Hui's operating conditions did

not utilize the time constant conditions recited in the claim. As held in *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) (footnote omitted).

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on "inherency" under 35 U.S.C. § 102, on "prima facie obviousness" under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products.

As Appellant did not meet the burden, we affirm the rejection of claim 1.

Claim 2

Appellant contends that "Hui does not disclose buffer conductivity, power supply capacitance, and electroporation chamber geometry as potential electroporation parameters - each of which is required by claim 2." Appeal Br. 6. The Examiner fully explained on pages 6–7 of the Answer how each of these parameters are present in Hui. We adopt these findings. As discussed in the *Claim Interpretation* section, merely selecting one of the recited parameters to use in the electroporation process meets the claim limitation. Consequently, the rejection of claim 2 is affirmed.

Claims 6, 7, 9, and 11

The Examiner identified disclosure in Hui that meets the limitations recited in dependent claims 6, 7, 8, and 11. Final Rej. 3, 5; Ans. 6–8.

Appellant contends "the Office arbitrarily selects an electric field strength and pulse duration from Hui without showing that the limitations of claims 6–7, 9, and 11, including the implicit limitations of claim 1, claim 2, and/or claim 9, exist in a single embodiment." Appeal Br. 6.

We do not agree.

Claim 6, depends from claim 2. Since Hui's process satisfies all the limitations of claim 2 (see above), carrying out the electroporation process utilizing an electric field value that falls within the scope of claim 6 would satisfy the claim without the need for any picking or choosing. The fact Hui may disclose a list of possible values that may be utilized in the process is not inconsistent with a finding that Hui is anticipatory to claim 6. A species which is specifically disclosed in a prior art reference is anticipatory even though it appears "without special emphasis in a longer list." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed. Cir. 2005). This same reasoning applies to claims 7, 9, and 11, each which depend from claim 1. The only claim that requires two different limitations is claim 11, but Hui explicitly teaches cells (claim 9) and loading them with DNA ("a chemical or biological agent" of claim 11). Hui 157, 160. Consequently, Appellant did not demonstrate reversible error in the Examiner's rejection.

OBVIOUSNESS REJECTION

The Examiner rejected claims 2–5 and 8 as obvious in view of Hui. Final Rej. 6. The Examiner found that the parameters recited in these claims were known optimizable variables. *Id.* at 7. The Examiner determined that it would have been obvious to the ordinary skilled worker to "optimize certain electroporation conditions related to buffer conductivity, power

supply capacitance, electroporation chamber geometry." *Id.* at 8. The Examiner stated optimization of ranges is prima facie obvious. *Id.*

Appellant contends that the portion of Hui cited by the Examiner "never suggests optimizing each of buffer conductivity, power supply capacitance, electroporation chamber geometry, and electric field strength for the purpose of achieving the limitations described in claim 1." Appeal Br. 7.

The claim does not require "optimizing" the parameters as asserted by Appellant. The claim limitations are satisfied if the parameters recited in the claim are met by Hui, or would have been obvious to one of ordinary skill in the art based on Hui's teachings. The Examiner explained how buffer conductivity (claim 3), capacitance (claim 4), chamber dimensions (claim 5), and pulse duration (claim 8) would either be inherent or optimizable based on explicit teachings in Hui. Ans. 9–12. We adopt the Examiner's findings and reasoning. *Id.* We also agree with the Examiner that Appellant has the burden to show that the ranges recited in the claims are "critical" to the claimed process, rather than simply being a range routinely selected by following Hui's teachings.

> The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. These cases have consistently held that in such a situation, the applicant must show that the particular range is *critical*, generally by showing that the claimed range achieves unexpected results relative to the prior art range.

In re Woodruff, 919 F.2d 1575, 1578 (Fed. Cir. 1990). (Internal citations omitted.)

In reaching the determination that claims 3, 4, 5, and 8 would have been obvious to one of ordinary skill in the art, we have not ignored the time constant requirement of claim 1. However, because the Examiner had sound basis for believing the time constants are met (Final Rej. 3), Appellant has the burden of showing that the Examiner erred. This was discussed in the anticipation rejection. Appellant has not provided adequate fact-based evidence that such time constants would not be achieved when following Hui's teachings.

SUMMARY

The anticipation rejection of claims 1, 2, 6, 7, 9, and 11 is affirmed.

The obviousness rejection of claims 2–5 is affirmed.

To the extent any of the claims were not separately argued, they fall with claims 1 and 2. 37 C.F.R. § 41.37(c)(1)(iv).

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED